

## **REMARKS**

This Amendment is fully responsive to the final Office Action mailed December 7, 2009.

### ***Objection to Drawings***

The Office Action (§ 2) notes that the previous Amendment was not accompanied by replacement drawing sheets, as had been indicated in the remarks to the previous Amendment. Therefore, those replacement drawing sheets 2 and 4 are submitted herewith. The only change in the replacement drawing sheets versus the original drawing sheets is that words have been added in boxes 23, 27 and 152.

### ***Claim Rejections Under 35 U.S.C. § 112***

The Office Action (§ 4) rejects claim 11 under 35 U.S.C. § 112, as failing to comply with the written description requirement. The applicants do not necessarily agree with the conclusion in the Office Action that the current specification fails to disclose / enable the limitation in claim 11 of monitoring a blood flow rate of the patient, in light of the knowledge of one of ordinary skill in this art. Nonetheless, claim 11 has been cancelled herein in order to speed prosecution.

### ***Interview***

The applicants very much appreciate the courtesy of the Interview which took place on March 16, 2010, and the opportunity it provided for the applicants to explain why they believe the pending claims contain limitations that patentably define over the references cited by the Examiner. The applicants agreed to provide those arguments in writing. Therefore, reconsideration and allowance of the pending claims is respectfully requested for the following reasons.

### ***Rejection of Claim 10 As Anticipated by Jackson***

The Office Action (§ 6) rejects claim 10 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,475,148 to Jackson et al. (hereafter "Jackson"). The Office Action concludes Jackson does not disclose the limitation of "during the CT scan", but that language in the claim may be ignored because it is non-limiting functional language. The applicants respectfully submit that language may not simply be ignored. Moreover, as discussed next, Jackson does not disclose monitoring the heart beat rate of a patient during a CT scan.

### ***Rejections of Claims 1 - 10 and 12 - 17 Based on Baker, Giesler and Jackson***

The Office Action (§§ 9 and 12) rejects claims 1-4, 7-10, 12-14 and 17 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,628,981 to Baker et al. (hereafter “Baker”), in view of “Noninvasive Visualization of Coronary Arteries Using Contrast-Enhanced Multidetector CT” to Giesler et al. (hereafter “Giesler”), and in further view of U.S. Patent No. 6,475,148 to Jackson et al. (hereafter “Jackson”). Moreover, the Office Action (§§ 10-11) rejects dependent claims 5, 6, 15 and 16 under 35 U.S.C. § 103(a) as unpatentable over Baker, Giesler and Jackson, and further in view of additional secondary references. These rejections are each based upon the conclusion that the parent independent claims 1, 8 and 10 are unpatentable as obvious over Baker in view of Giesler and additionally in view of Jackson. It is requested that these rejections be reconsidered and withdrawn, because none of the cited references discloses monitoring the heart beat rate of a patient during a CT scan and rupturing a drug container on the basis of the monitored heart beat rate, as recited in each of the parent independent claims.

Baker does not disclose monitoring a heart beat rate of the patient during a CT scan, nor does Baker disclose rupturing drug containers on the basis of the monitored heart beat rate. Rather, Baker discloses using an EKG 46 and associated SYNC unit 48 during a CT scan to determine whether the heart is in the systole phase or the diastole phase of the cardiac cycle, or the point in time when such phases begin (Baker, col. 2, lines 1-18 and col. 4, lines 1-15). The signal from the SYNC unit 48 in Baker enables an x-ray controller 32 to synchronize x-ray production during a selected portion of the cardiac cycle (Baker, col. 4, lines 26-38). Baker discloses that, advantageously, x-ray attenuation data is collected during a resting period within the cardiac cycle, typically corresponding to the diastole phase (Baker, col. 2, lines 7-18 and col. 4, lines 39-44).

Thus Baker operates on the basis of the patient’s cardiac cycle, not on the basis of a monitored heart beat rate, during the CT imaging scan. The patient’s heart beat rate during the CT scan, as measured for example in beats per minute, does not determine or affect any imaging procedure applied in Baker. Rather, Baker discloses attempting to determine the phase of the patient’s cardiac cycle during the CT imaging scan, and then acting on that basis, regardless of how fast the heart is actually beating. Indeed, to the extent a patient’s heart beat rate plays any role at all in Baker, that role is pre-determined before the CT imaging scan is begun based on a predicted heart rate with a predicted range. See Baker, col. 4, line 45 to col. 5, line 9; see also Baker, col. 5, line 55

to col. 6, line 26. Performing an imaging scan based on such a predicted heart beat rate is very different from performing an imaging scan based on monitoring the patient's actual heart beat rate during the imaging scan.

Turning to Giesler, like Baker it does not disclose either monitoring a heart beat rate of the patient during the CT scan, or rupturing a drug container on the basis of the monitored heart beat rate. Giesler studies the influence of heart rate on the presence of motion artifacts and on accuracy in detecting coronary artery stenoses (Giesler, page 1, col. 1 to col. 2). Giesler ultimately concludes "a useful approach might be to limit the use of MDCT [multidetector CT] for coronary artery visualization to patients with lower heart rates or to use pharmacologic interventions (e.g.,  $\beta$ -blockers) during the scanning to enhance image quality and accuracy in the identification of coronary stenoses" (Giesler, page 914, col. 3). Thus, at most, Giesler discloses giving the patient a drug before the CT imaging scan begins to lower a patient's heart beat rate and thereby reduce motion artifacts. Giesler does not disclose monitoring a heart beat rate of the patient during the CT scan, or applying a drug on the basis of the monitored heart beat rate, as recited in claim 1.

As to Jackson, like Baker and Giesler it does not disclose monitoring a heart beat rate of the patient during the CT scan, or rupturing a drug container on the basis of the monitored heart beat rate. Jackson discloses a method and system for delivering drugs carried by microspheres, using an ultrasound system to destroy the microspheres in a specific localized area or at a specific time (Jackson, col. 1, lines 28-35). Concerning the timing aspect of Jackson, a trigger may respond to a heart or breathing cycle (Jackson, col. 1, lines 44-48 and col. 3, lines 39-51). For example, the user may identify a time or time window within the cardiac cycle to apply the drug, such as end diastole for myocardial therapy (Jackson, col. 7, lines 25-39). However, Jackson does not disclose using any of its method and system during a CT imaging scan. Moreover, much like Baker, the trigger / synchronization disclosed in Jackson correlates to a specific point or points in the cardiac cycle, not a monitored heart beat rate as claimed in the present independent claims 1, 8 and 10. Thus Jackson does not disclose monitoring a heart beat rate, or taking any action on the basis of a monitored heart beat rate, during a CT scan.

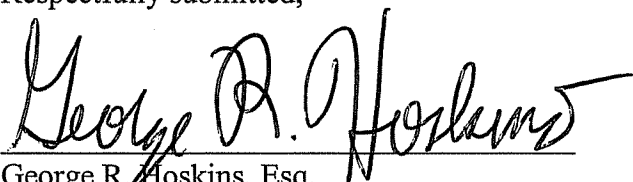
Thus, there is no disclosure in any one of Baker, Giesler or Jackson of monitoring a heart beat rate of the patient during the CT scan, or rupturing a drug container on the basis of the monitored heart beat rate, as recited in independent claims 1, 8 and 10. For at least that reason, it is

respectfully submitted that the rejections of claims 1-10 and 12-17 should be reconsidered and withdrawn.

***Conclusion***

This Amendment is fully responsive to the final Office Action mailed December 7, 2009. It is respectfully submitted that the claims contain limitations that patentably define over the references cited by the Examiner, for the reasons provided in the remarks above. Therefore, reconsideration and allowance of the pending claims is appropriate and respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "George R. Hoskins". The signature is written in a cursive style with a horizontal line underneath the name.

George R. Hoskins, Esq.  
Calfee, Halter & Griswold LLP  
800 Superior Avenue, Suite 1400  
Cleveland, Ohio 44114  
(216) 622-8200